K030909

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

APR 1 0 2003

Submitters Name:	*aap* Implantate AG Lorenzweg 5 12099 Berlin Germany Phone: +49 30 750 19 0 Fax: +49 30 750 19 111
Contact Name:	Dipl.-Ing. Christian Abel, Director Quality Management
Name of Device:	*aap* AcroPlate
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
Common/Usual Name:	*aap* AcroPlate
Proprietary Name:	*aap* AcroPlate
Classification:	Class II, Single/multiple component metallic bone fixation appliances and accessories, CFR Chapter I, Title 21 § 888.3030, # 87 H RS #

Performance Standards: Devices are manufactured according to cGMP's, applicable ASTM requirements, and applicable harmonised standards ISO 9001 / EN 46001.

Material Composition: The *aap* AcroPlate is manufactured of
Titanium Alloy (Ti 6Al 4V E.L.I. = ASTM F136), and 316L Stainless Steel (ASTM F 138)

Intended Use: The *aap* AcroPlate with 3 holes is intended for use for healing an AC-joint injury of the Tossi III and Rockwood III-V.
The *aap* AcroPlate with 4 holes is intended for use for healing an lateral fracture of the Clavicula.

Device Description: The *aap* AcroPlate is manufactured of Titanium Alloy (Ti Al6 V4 E.L.I.) and 316 L Stainless Steel. The *aap* AcroPlate is available with 3 or 4 holes.

Predicate Devices for Substantial Equivalence:
K915315 *aap* Bone Plate

Comparision of Technological Characteristics: The *aap* AcroPlate is substantially equivalent to the predicate devices with respect to physical/technical and material characteristics.

Sterilisation Information: The devices are distributed in non sterile, recommendations for sterilization are contained in package insert. Note: These devices are sterilised by end users utilizing the approved/outlined guidelines found in the AAMI Guideline "Good Hospital Practice: Steam Sterilisation and Sterility Assurance" and in ANSI/AAMI/ISO 11737 guidelines to achieve the acceptable Sterility Assurance Level (SAL).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2003

Dipl.-Ing. Christian Abel
Quality Management, Research and Development
aap Implantate AG
Lorenzweg 5
12099 Berlin
Germany

Re: K030909
Trade/Device Name: aap AcroPlate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: March 19, 2003
Received: March 24, 2003

Dear Mr. Abel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K030909

Device Name: *aap* AcroPlate

Indications for Use:

The *aap* AcroPlate is intended for use on:

- Acromioclavicular dislocations Type Tossi III and Type Rockwood III-V
- Extremely lateral fractures of the clavicula

for Mark N Milham

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030909